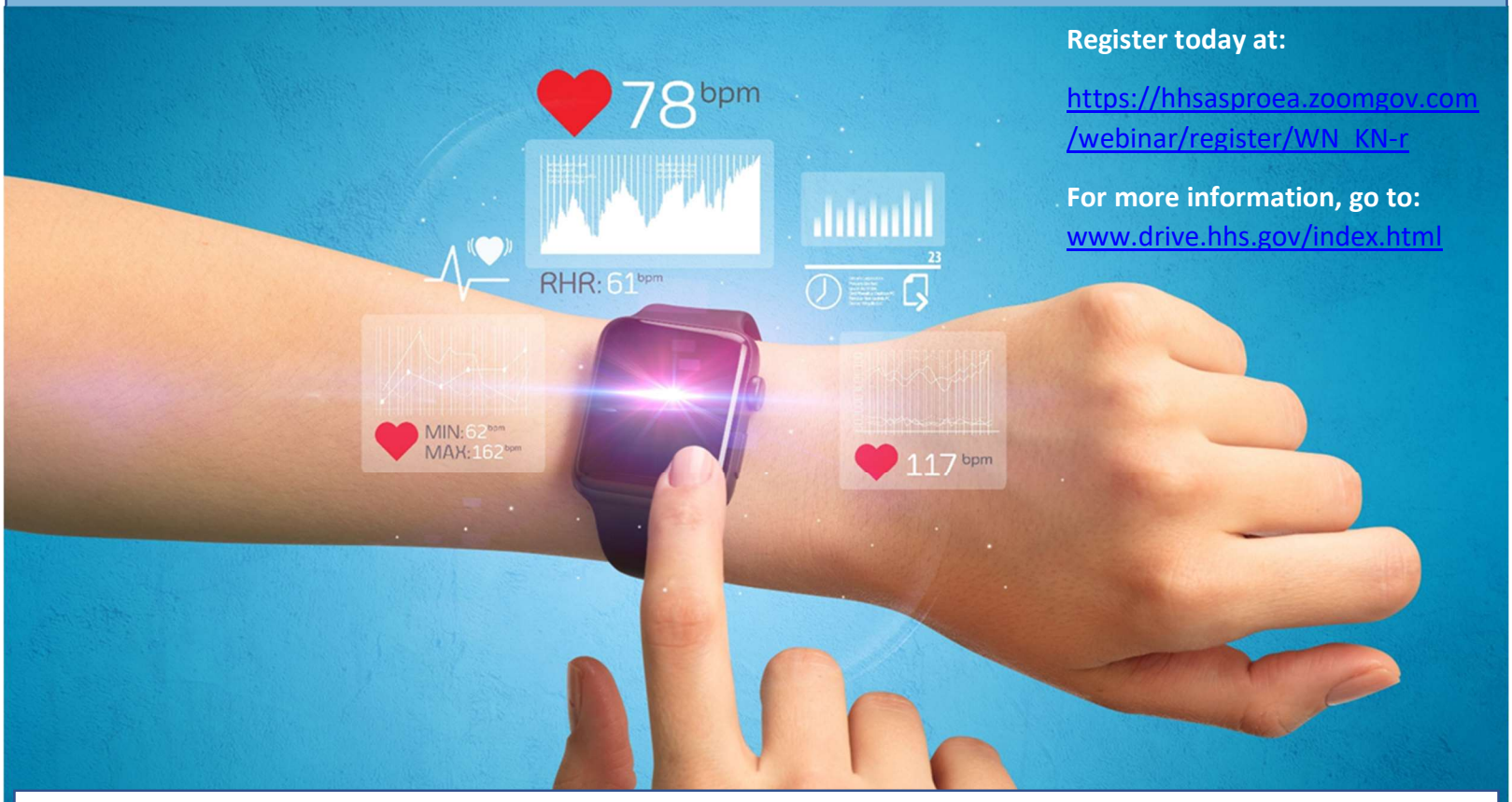
2021 Federal Wearables Summit

Wearable Sensors for Monitoring Health and Health Quality

The 2021 Federal Wearables Summit is a broad interagency effort intended to bring the discussion on wearable sensors for monitoring health and health quality closer to all citizens. The Summit is open to the public and will address issues of interest, such as the perspectives of patients and medical care professionals, data security specialists, the regulatory bodies, and federal agencies.

Public meeting
August 31, 2021
10:00 AM – 3:30 PM ET
Virtual event



Register today at:

https://hhsasproea.zoomgov.com/webinar/register/WN_KN-r

For more information, go to:
www.drive.hhs.gov/index.html

DARPA | DEFENSE INNOVATION UNIT | ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE | BARDA | DRIVe | NIH National Institutes of Health *Turning Discovery Into Health*

Biomedical Advanced Research and Development Authority – BARDA
Defense Threat Reduction Agency – DTRA
Defense Advanced Research Projects Agency – DARPA
Defense Innovation Unit – DIU
National Institutes of Health – NIH

welcome you to the

2021 Federal Wearables Summit
Wearable Sensors for Monitoring Health and Health Quality

Public virtual meeting

The Biomedical Advanced Research and Development Authority, the Defense Threat Reduction Agency, the Defense Advanced Research Projects Agency, the Defense Innovation Unit, and the National Institutes of Health welcome you to the 2021 Federal Wearables Summit to discuss wearable sensors for monitoring health and health quality. This meeting is open to the public, as well as healthcare professionals and subject matter experts from the government, academic, and private sectors. The goal of this broad interagency effort is to share with the public the utility of wearable sensors in health monitoring and how these devices can integrate with a person's lifestyle and medical care. This meeting will foster discussions around medical care providers' perspectives, consumer health care experience, data security, funding and regulatory aspects, and future directions in wearables for health monitoring.

Thank you for joining us. We hope you enjoy the 2021 Federal Wearables Summit!

Free registration for Zoom meeting at drive.hhs.gov

We thank the members of the steering committee:

Mark Wrobel, DARPA

Christopher Kiley, DTRA

Niels Olson, DIU

Šeila Selimović, BARDA

Tiffani Lash, NIH

Andrew Weitz, NIH

Dana Wolff-Hughes, NIH

AGENDA: August 31st, 2021 (Eastern Time zone)	
1000 – 1015	**Welcoming Remarks and Introductions**
1000 – 1005	**Welcome** Speaker: Gary Disbrow, PhD. Director, HHS/ASPR/BARDA
1005 – 1015	**Summit Introduction, Goals, and Objectives** Speaker: Sandeep Patel, PhD. Director, HHS/ASPR/BARDA/DRIVe
1015 – 1230	**Session I**
1015 – 1100	**Medical Care Provider's Perspective** Speaker: Steve Xu, MD MSc FAAD. CEO, Sibel Health / Northwestern Memorial Hospital Moderator: CAPT Hui-Hsing Wong, MD, JD. Clinical Advisor, HHS/ASPR/BARDA
1100 – 1145	**Technology and The Consumer Health Care Experience Panel** • Susannah Fox. Principal, Internet Geologist LLC • Dana Lewis. Creator, Do-It-Yourself-Pancreas-System Moderator: Melinda J. Hamer, MD, MPH, FACEP LTC, MC, US Army. Director, WRAIR / Clinical Trials Center
1145 – 1230	**Data Security** Speaker: Jennifer Goldsack, MChem, MA, MBA. Executive Director, Digital Medicine Society (DiMe) Moderator: Niels Olson
1230 – 1300	**BREAK**

1300 – 1515	Session II
1300 – 1345	**Federally Funded Research & Development Panel** • Šeila Selimović, PhD. Program Manager, HHS/ASPR/BARDA/DRIVe • Tiffani Lash, PhD. Health Scientist Administrator, NIH/NIBIB • Dana Wolff-Hughes, PhD. Program Director, NIH/NCI Moderator: Andrew Weitz, PhD. Program Director, NIH/NIBIB
1345 – 1430	**Stakeholder Panel - The Future of Wearables for Health Monitoring** • Marion Couch, PhD, MBA, FACS. Senior Vice President / Chief Medical Officer, Cambia • Bakul Patel, MBA. Director, FDA / Digital Center of Excellence Moderator: Kimberly Sciarretta, PhD. Program Manager, HHS/ASPR/BARDA/DRIVe
1430 – 1515	**Wearables and Behavior** Speaker: Wendy Nilsen, PhD. Acting Deputy Division Director, NSF/IIS Moderator: Dana Wolff-Hughes, PhD. Program Director, NIH/NCI
1515 – 1530	**Closing Remarks**
1515 – 1530	**Wrap-up** Speaker: Šeila Selimović, PhD. Program Manager, HHS/ASPR/BARDA/DRIVe

Biographies

Gary Disbrow, PhD

Deputy Assistant Secretary for Preparedness and Response
HHS / ASPR

Director
HHS / ASPR / BARDA (Biomedical Advanced Research and Development Authority)

Dr. Disbrow joined BARDA in January of 2007 and has held a variety of positions related to the advanced development and procurement of medical countermeasures against an array of threats to national security and public health. Prior to becoming the BARDA Director, Dr. Disbrow served as acting BARDA Director, Deputy Assistant Secretary of ASPR and Medical Countermeasures Program Director. In October 2013, Dr. Disbrow was named Acting Director of the Chemical, Biological, Radiological and Nuclear (CBRN) Division and was subsequently named the Director of the Division in December of 2014. During that time, the CBRN Division built a robust pipeline of candidate products under advanced research and development. In 2014 and 2015, Dr. Disbrow was identified as the Ebola Incident Coordinator for BARDA and worked closely with the BARDA Director on funding needs, development of candidate products, and was the primary liaison for BARDA across the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). These efforts led to the first licensed Ebola vaccine, ERBEVO licensed in December 2019. October 2008, Dr. Disbrow began serving as the Deputy Director of the CBRN Division of Countermeasures and oversaw the budget and programs for both advanced research and development and Project BioShield efforts. Upon joining BARDA in January 2007, Dr. Disbrow began working on the smallpox vaccine program. Dr. Disbrow played a key role in awarding the first contract under Project BioShield using the authorities for advanced payment and milestone payments provided under the Pandemic and All-Hazards Preparedness Act (2006). JYNNEOS was licensed in September 2019. Prior to joining BARDA, Dr. Disbrow was an Assistant Professor of Oncology and Pathology at Georgetown Medical Center where he worked on human papillomavirus (HPV) vaccines and therapeutics. Dr. Disbrow has previously worked at W.R. Grace, Kodak, and Genecor. Dr. Disbrow attended the University of Rochester and Georgetown University for his undergraduate and Ph.D. respectively.

Marion Couch, MD, PhD, MBA, FACS

Senior Vice President, Health Care Services; Chief Medical Officer
Cambia Health Solutions

Marion is currently the Senior Vice President of Health Care Services and the Chief Medical Officer at Cambia Health Solutions. This company administers the Regence Blue Cross Blue Shield (BCBS) health insurance plans which span four state and serve 3.1 million members. She leads medical strategy for all of Cambia and provides executive leadership for the Regence BCBS plans. This includes medical care initiatives, quality programs, value-based care plans, utilization management, pharmacy services, provider relations, network management, payment integrity, and cost stewardship. Prior to this role, Marion was the (Career) Senior Medical Advisor in the Office of the Administrator at the Centers for Medicare & Medicaid Services (CMS) in Washington, DC, which had a $1.3 trillion annual budget and insured 145 Americans. In this cross-cutting role within the agency, she reported directly to the Administrator to work on policy creation, quality, and promoting the vast expansion of telehealth during the pandemic. Marion was also involved in developing value-based payment models in the Center for Medicare and Medicaid Innovation, with special emphasis on longitudinal care for chronic conditions that often are treated with surgery. Before joining CMS, she held senior leadership roles at several large medical centers. Marion has previously served as the Chair of the Indiana University Health Physician Board. She has been a physician executive in two large medical groups where she served as the Physician Executive of Surgical Services and as the Vice President of Finance. She has also been the Chair of two surgical departments and was Surgeon-in-Chief at a medical center. Marion has served as President of two national professional medical societies. Marion is a trained head and neck surgeon with advanced microvascular surgery training. She received her medical degree from Rush Medical College. Her residency training was at Johns Hopkins Hospital. Her MBA is from the Duke University Fuqua Business School with a Concentration in Healthcare Management.

Susannah Fox

Health and Information Technology Researcher & Principal
Internet Geologist, LLC

Susannah Fox is a health and information technology researcher based in Washington, DC. She is a former Chief Technology Officer for the U.S. Department of Health and Human Services during the Obama Administration, where she led an open data and innovation lab. In 2014-15, she was the entrepreneur-in-residence at the Robert Wood Johnson Foundation. For 14 years she directed the health portfolio at the Pew Research Center's Internet Project.

Jennifer Goldsack, MChem, MA, MBA

Executive Director
Digital Medicine Society (DiMe)

Jennifer C. Goldsack co-founded and serves as the Executive Director of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. Jen's research focuses on applied approaches to the safe, effective, and equitable use of digital technologies to improve health, healthcare, and health research. She is a member of the Roundtable on Genomics and Precision Health at the National Academies of Science, Engineering and Medicine. Previously, Jen spent several years at the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA. There, she led development and implementation of several projects within CTTI's Digital Program and was the operational co-lead on the first randomized clinical trial using FDA's Sentinel System. Jen spent five years working in research at the Hospital of the University of Pennsylvania, first in Outcomes Research in the Department of Surgery and later in the Department of Medicine. More recently, she helped launch the Value Institute, a pragmatic research and innovation center embedded in a large academic medical center in Delaware. Jen earned her master's degree in chemistry from the University of Oxford, England, her masters in the history and sociology of medicine from the University of Pennsylvania, and her MBA from the George Washington University. Additionally, she is a certified Lean Six Sigma Green Belt and a Certified Professional in Healthcare Quality. Ms Goldsack is a retired athlete, formerly a Pan American Games Champion, Olympian, and World Championship silver medalist.

LTC Melinda Hamer, MD, MPH

Senior Medical Advisor
HHS / ASPR / BARDA / DRIVe (Division of Research, Innovation, and Ventures)
LTC, US Army

Melinda Hamer MD, MPH was the Director of the Clinical Trials Center at the Walter Reed Army Institute of Research 2017-2021 and is currently detailed to the Department of Health and Human Services, Biomedical Advanced Research and Development Authority as a Senior Medical Advisor. She has served as a principal and associate investigator for more than 20 FDA regulated and other clinical trials, to include multiple first-in-human vaccine trials, and the largest in history controlled human malaria challenge trial, and managed an annual budget of more than $10 million. She was principal investigator of the recently completed first-in-human trial of a novel Marburg virus vaccine, in collaboration with the NIH's Vaccine Research Center, and served as an investigator on multiple COVID-19 related clinical trials. She is a U.S. Army flight surgeon and board-certified emergency physician, and an Associate Professor in the Department of Military and Emergency Medicine at the Uniformed Services University of the Health Sciences in Bethesda, Maryland. She also holds a part-time appointment as an Assistant Professor in the Department of Emergency Medicine at the George Washington University Department of Emergency Medicine. Dr. Hamer is also the co-author of official U.S. Government and Institute of Medicine reports on health care reconstruction efforts in Iraq and has over 40 peer-reviewed publications as well as dozens of national abstract presentations and other reports.

Tiffani Bailey Lash, PhD

Program Director
NIH / NIBIB

Dr. Tiffani Bailey Lash serves as a Health Scientist Administrator for the National Institutes of Biomedical Imaging and Bioengineering (NIBIB) at the National Institutes of Health (NIH). Dr. Lash is the Program Director for the NIH Rapid Acceleration of Diagnostics (RADx℠) Tech and Advanced Technology Platforms initiative, NIH Technology Accelerator Challenge (NTAC), and the NIBIB Point of Care Technologies Research Network. She also serves as co-coordinator for the NIH Common Fund's Harnessing Data Science for Health Discovery and Innovation in Africa. Her research portfolio includes Point of Care Technologies and Digital Health, both with the goal of developing biomedical technologies through collaborative efforts that merge scientific and technological capabilities with clinical need. Prior to her current position, Dr. Lash worked within the NIH's science policy administration. During that time, she worked at the National Institute of General Medical Sciences and National Heart Lung and Blood Institute, as well as the NIH Office of the Director. Dr. Lash has been selected as a science policy fellow for both the American Association for the Advancement of Science (AAAS) and the National Academy of Engineering. She also has a background in small business innovation and intellectual property. Dr. Lash earned her Ph.D. in Physical Chemistry from North Carolina State University via a collaboration between the Departments of Chemistry and Chemical and Biomolecular Engineering. Her interdisciplinary research interests include microfluidics, biopolymers with controlled molecular architecture, and biosensor technologies.

Dana Lewis

Independent Researcher
#OpenAPS

After building her own DIY "artificial pancreas," Dana Lewis helped found the open source artificial pancreas movement (known as "OpenAPS"), making safe and effective artificial pancreas technology available (sooner) for people with diabetes around the world. She is the Principal Investigator for a Robert Wood Johnson Foundation funded grant project to work to scale patient-led innovation and scientific discovery in more patient communities, as well as co-PI on numerous other diabetes data science and medical device wearable-related grant projects. She authored the book, "Automated Insulin Delivery: How artificial pancreas "closed loop" systems can aid you in living with diabetes", to help more people understand automated insulin delivery systems.

Wendy Nilsen, PhD

Acting Deputy Division Director
NSF / Computer & Information Science & Engineering Directorate / Information and Intelligent Systems

Wendy Nilsen, Ph.D. is the Acting Deputy Division Director in the Information and Intelligent Systems Division of the Computer and Information Science and Engineering Directorate at NSF. She is also the lead Program Director in the Smart Health program. Her work has focused on the intersection of computing and human functioning. Her interests span the areas of sensing, analytics, cyber-physical systems, information systems, machine learning, artificial intelligence, and robotics. She also serves as cochair of the Health Information Technology Research and Development working group of the Networking and Information Technology Research and Development Program and, serving on numerous federal technology initiatives. Prior to joining NSF, Wendy was at the National Institutes of Health.

CDR Niels Olson, MD

Chief Medical Officer
Defense Innovation Unit
CDR MC USN

Niels Olson is a board-certified pathologist and the Chief Medical Officer of the Defense Innovation Unit in Mountain View, California. His previous duty stations include Laboratory Medical Director at Naval Hospital Guam, staff pathologist at Naval Hospital Camp Pendleton, and General Medical Officer for Surface Forces Pacific. He completed AP/CP residency at Naval Medical Center San Diego. His undergraduate degree is in Physics and prior to medical school he served 7 years as a Surface Warfare Officer in the US Navy. He oversees research programs in machine learning for a broad spectrum of anatomic pathology applications, augmented reality microscopy, artificial intelligence applications in radiology, and distributed sensors in austere environments.

Bakul Patel, MBA

Director, Digital Health Center of Excellence
Director, Digital Health Division
FDA / CDRH (Center for Devices and Radiological Health)

Bakul Patel is the Director for Digital Health Center of Excellence at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.
Mr. Patel, in 2013, created the term "software as a medical device" (SaMD) and under his leadership the *International Medical Device Regulators Forum* (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA. Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products. Prior to joining FDA, Mr. Patel held key leadership positions in several sectors including telecommunications industry, semiconductor capital equipment industry, wireless industry, and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Sandeep Patel, PhD

Director
HHS / ASPR / BARDA / DRIVe (Division of Research Innovation, and Ventures)

Sandeep Patel oversees a diverse portfolio of health security innovations to address current and emerging threats. He is an entrepreneur and restless innovator who uses his experience to advance high impact science, build new products, and launch new programs and initiatives that focus on health and wellness. Sandeep's experiences highlight his commitment to public service as evidenced in his prior roles in the US Department of Health and Human Services (HHS) where he focused on advancing innovative policies and funding solutions to complex, long-standing health-related problems. He co-founded and led a new $35M+ public-private partnership, KidneyX, that advanced development and lowered the commercialization risks of breakthrough therapies for kidney disease, notably an implantable artificial kidney to displace dialysis. He spearheaded the Advancing American Kidney Health Initiative and he built a $50M program scaling the use of incentive prizes and crowdsourcing as 21st century problem-solving tools across the family of HHS agencies. Previously, Sandeep served in a number of science policy roles, including as a Mirzayan Science and Technology Policy Fellow at the National Academy of Sciences and as a scientific consultant for Thomson Reuters. He is the recipient of the American Society of Nephrology's President's Medal, honoring those who have transformed kidney care, for which he was also awarded a Secretary's Distinguished Service award. He founded a company in Uganda focused on rapid design and development of novel products for agriculture and health using portable 3D printing services. He holds a PhD in physical chemistry from the Georgia Institute of Technology and a BA in chemistry from Washington University in St. Louis.

Kimberly Sciarretta, PhD

Program Manager
HHS / ASPR / BARDA / DRIVe (Division of Research Innovation, and Ventures)

Kimberly Sciarretta, PhD is the Solving Sepsis Program Manager within the Division of Research Innovation and Ventures (DRIVe), Biomedical Advanced Research and Development Authority (BARDA), part of the Assistant Secretary for Preparedness and Response (ASPR), within the United States Department of Health and Human Services (HHS). Previously Dr. Sciarretta was a Project Officer within the BARDA CBRN Division, and prior to that, was a technical consultant to multiple US Government Agencies. Dr. Sciarretta was one of the inaugural members of DRIVe and is leading efforts towards improving patient outcomes for sepsis through strategic interagency activities and critical technology investments with external partners. Dr. Sciarretta received her PhD from the University of Chicago in Molecular Genetics and Cell Biology. Her expertise broadly spans medical countermeasure development, biochemistry, synthetic biology, advanced manufacturing, and chemical and biological defense technologies.

Šeila Selimović, PhD

Program Manager
HHS / ASPR / BARDA / DRIVe (Division of Research Innovation, and Ventures)

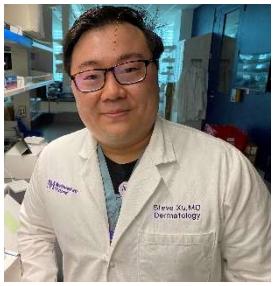
Dr. Šeila Selimović oversees multiple programs in BARDA's Division of Research, Innovation, and Ventures that focus on de-risking transformational technologies in the health security space. Prior to BARDA, Šeila was a Program Director at the National Institute of Biomedical Imaging and Bioengineering, working in the sensors and tissue engineering areas, and a AAAS Science and Technology Policy Fellow at the US Department of State, where she helped spear-head the first U.S.-Poland Innovation Partnership. Šeila completed her PhD in Condensed Matter Physics at Brandeis University, funded by an NSF Traineeship, and pursed a postdoctoral fellowship at Harvard Medical School / Brigham & Women's Hospital.

Andrew Weitz, PhD

Program Director
NIH / NIBIB / Division of Health Informatics Technologies

Dr. Andrew Weitz joined the NIBIB as a Program Director in 2017. He leads digital health strategy for the Rapid Acceleration of Diagnostics (RADx) initiative. Dr. Weitz also provides programmatic oversight to Stimulating Peripheral Activity to Relieve Conditions (SPARC), a program focused on electrical stimulation of peripheral nerves for treating various diseases and conditions.

Steve Xu, MD, MSc



Medical Director
Querrey Simpson Institute for Bioelectronics, Northwestern University

Assistant Professor
Departments of Dermatology, Biomedical Engineering, and Pediatrics, Northwestern University

Steve Xu MD, MSc received his undergraduate degree in bioengineering from Rice University summa cum laude. He completed his medical training at Harvard Medical School with special honors as a Soros Fellow, and a Masters in Health Policy and Finance with Merit from The London School of Economics as a Marshall Scholar. Finally, he completed an NIH-funded T32 post-doctoral fellowship in Northwestern's Department of Materials Science and Engineering under John Rogers PhD. Dr. Xu has authored more than 100 peer-reviewed publications and listed as an inventor on 11 pending and granted patents. He has developed several wearable technologies with a focus on maternal, fetal, and neonatal health. His publications have appeared in The New England Journal of Medicine, Science, and Nature garnering press attention from sources such as The New York Times, CNN, and The Washington Post. As part of his collaborative research efforts, several of his joint inventions have been licensed to both small and large companies for commercialization.

Dana L. Wolff-Hughes, PhD

Program Officer
NIH / NCI / Division of Cancer Control and Population Sciences, Risk Factor Assessment Branch

Dr. Dana Wolff-Hughes is a Program Director in the Risk Factor Assessment Branch (RFAB) of the Epidemiology and Genomics Research Program (EGRP) in NCI's Division of Cancer Control and Population Sciences (DCCPS). In this capacity, she supports work which validates and utilizes digital technology for cancer risk factor assessment (including physical activity, sedentary behavior, and sleep) in research and population surveillance. Dr. Wolff-Hughes's scientific interests include novel methods and analytical approaches for risk factor assessment using digital technology, health information technology, and temporally linked contextual data. She is particularly interested in how the accuracy of physical activity measures influence dose response relationships, with a focus on methods to better interpret and understand data from digital technology.

CAPT Hui-Hsing Wong, MD, JD

Senior Medical Advisor
HHS / ASPR / BARDA / Division of Clinical Development
CAPT PHS

Hui-Hsing Wong is a CAPT in the Commissioned Corps of the U.S. Public Health Service and a medical advisor to the Division of Research, Innovation, and Ventures (DRIVe) at BARDA. She has spent almost 15 years of her HHS career working on medical product development and safety, first as a primary reviewer at FDA; then in policy development at the Office of the Secretary where she oversaw the initial development of an active surveillance program for drug safety; reviewed FDA policies, guidances, and regulations at the Office of the Secretary; served as a strategic advisor for KidneyX; and led research projects on the econometric and regulatory aspects of medical product development, particularly incentives for development. Dr. Wong received a BS from Yale University, a JD from Columbia School of Law, an MD from Baylor College of Medicine. She trained in pediatrics at the Johns Hopkins Hospital. She is a member of the New York State Bar, licensed to practice medicine in Maryland, and is board-certified in pediatrics. She is a part-time staff pediatrician at the Walter Reed National Military Medical Center and an assistant professor of pediatrics at the Uniformed Services University of the Health Sciences in Bethesda, MD.